REMARKS

The specification has been amended to recite correct cross-reference information. In addition, typographical errors concerning cited patents and extra words and letters were corrected It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Objection

The specification was objected to because the patent number 5,375,659 listed on page 4, line 12, of the captioned application appears to be incorrect. (Paper No. 03012004 ("Office Action") at 2.) The Examiner's careful reading of this section of the specification is most appreciated. The specification has been amended in view of the Examiner's comments. In addition, the application was reviewed for additional typographical errors and such errors that were located are corrected in this Paper. It is intended that this objection is now moot and should be withdrawn.

Obviousness Rejections

Claims 18-38 were rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 4,552,899 ("Sunshine") (Office Action at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Sunshine discloses

> **Pharmaceutical compositions and methods of using same comprising a non-steroidal anti-inflammatory drug in combination with at least one other active component selected from an antihistamine, decongestant, cough suppressant (antitussive) or expectorant are provided for the relief of cough, cold and cold-like symptoms.** Abstract;

> **It is, therefore, a primary object of the present invention to provide pharmaceutical compositions of matter comprising an analgesically effective amount of a non-steroidal anti-inflammatory drug (NSAID) in combination with at least one of an antihistamine, decongestant, cough suppressant, expectorant and, optionally, including pharmaceutically acceptable carriers therefor.** Col. 1;

The non-steroidal anti-inflammatory drugs (NSAID's) for use in the pharmaceutical compositions and methods of use of the present invention may be selected from any of the following categories:

(1) The propionic acid derivatives;

(2) The acetic acid derivatives;

(3) The fenamic acid derivatives;

(4) The biphenylcarboxylic acid derivatives; and

(5) The oxicams.

Accordingly, the term "NSAID" as used herein is intended to mean any non-narcotic analgesic non-steroidal anti-inflammatory compound, including the pharmaceutically acceptable non-toxic salts thereof, falling within one of the five structural categories above but excluding aspirin, acetaminophen and phenacetin. Col. 3;

Of the propionic acid derivatives for use herein, ibuprofen, naproxen, flurbiprofen, fenoprofen, ketoprofen, suprofen, fenbufen, and fluprofen may be mentioned as particularly preferred compounds.

Of the acetic acid derivatives, presently preferred members include tolmetin sodium, zomepirac, sulindac and indomethacin.

Of the fenamic acid derivatives, particularly preferred compounds include mefenamic acid and meclofenamate sodium.

The particularly preferred biphenylcarboxylic acid derivatives for use in the present invention include diflunisal and flufenisal.

The particularly advantageous oxicams include piroxicam, sudoxicam and isoxicam. Col. 3;

preferred.

With respect to the dosage amount of the non-steroidal anti-inflammatory drugs in the compositions of the invention, although the specific dose will vary depending upon the age and weight of the patient, the severity of the symptons, the incidence of side effects and the like, for humans, typical effective analgesic amounts of presently preferred NSAID's for use in unit dose compositions of the invention are about 100–500 mg diflunisal, about 25–100 mg zomepirac sodium, about 50–400 mg ibuprofen, most preferably 100–200 mg, about 125–500 mg naproxen, about 25–100 mg flurbiprofen, about 50–100 mg fenoprofen, about 10–20 mg piroxicam, about 125–250 mg mefenamic acid, about 100–400 mg fenbufen or about 25–50 mg ketoprofen; however, greater or lesser amounts may be employed if desired or necessary. With respect to the compounds set forth hereinabove falling within the propionic acid derivative category, suitable dosage ranges for these compounds will generally fall within the range of 25 mg to 600 mg in each unit dose.

A complete description of the various NSAID's, including acceptable analgesically effective amounts thereof for use in unit dose compositions of the present invention also appears in applicants co-pending U.S. application Ser. Nos. 474,358, filed Mar. 11, 1983 and 578,288, filed Feb. 8, 1984, the entire disclosures of which are incorporated herein by reference. Col. 4;

In the pharmaceutical compositions and methods of the present invention, the foregoing active ingredients will be combined with the non-steroidal anti-inflammatory drug(s) and will typically be administered in admixture with suitable pharmaceutical diluents, excipients or carriers (collectively referred to herein as "carrier" materials) suitably selected with respect to the intended form of administration, i.e., oral tablets, capsules, elixirs, syrups, etc. and consistent with conventional pharmaceutical practices. For instance, for oral administration in the form of tablets or capsules, the active drug components may be combined with any oral non-toxic pharmaceutically acceptable inert carrier such as lactose, starch, sucrose, cellulose, magnesium stearate, dicalcium phosphate, calcium sulfate, mannitol, ethyl alcohol (liquid forms) and the like. Moreover, when desired or necessary, suitable binders, lubricants, disintegrating agents and coloring agents can also be incorporated in the mixture. Suitable binders include

Col. 5;

starch, gelatin, natural sugars, corn sweeteners, natura and synthetic gums such as acacia, sodium alginate carboxymethylcellulose, polyethylene glycol anc waxes. Among the lubricants there may be mentionec for use in these dosage forms, boric acid, sodium benzo ate, sodium acetate, sodium chloride, etc. Disintegra tors include, without limitation, starch, methylcellulose agar, bentonite, guar gum, etc. Sweetening and flavor ing agents and preservatives can also be included where appropriate.

Col. 6;

In making the rejection, the Examiner asserted that Sunshine "combines NSAID's such as ibuprofen in does from 50 to 400 mg or in general propionic acid derivatives of from 25 mg to about 600 mg with pseudoephedrine for us as a preserved syrup formulation (column 12-13, lines 50-9)."(Office Action at 3.). The Examiner further asserted that "[t]he composition is administered in admixture with suitable pharmaceutical diluents, excipient and carriers suitably selected with respct to the intended form of administration, i.e., oral tablets, capsules, elixirs, syrups, etc." (*Id. at 3-4.*)

The Examiner interpreted claims 18-36 as being "drawn to a composition comprising pharmaceutically effective amounts of an amine and a non-steroidal anti-inflammatory drug (NSAID), suspended in a liquid medium wherein the suspension comprises at least one suspending agent and taste masking agent and wherein the composition provides an enhances absorption rate of the amine into the blood of a human compared with a corresponding composition comprising the amine but not the NSAID."

(*Id.* at 3.) The Examiner characterized the dependent claims as being "drawn to suspending agents and to dosages of ibuprofen /pseudoephedrine." (*Id.*) Finally, the Examiner asserted that "[c]laims 26-28 and 34-36 are drawn to the enhanced absorption rate indicated by AUC and CMAX." (*Id.*)

1) The Examiner acknowledged, however, that Sunshine differs from the presently claimed invention in that "[i]t does not specifically recite a suspension." (Office Action at 4.)

To fill the acknowledged gap, the Examiner relied upon the fact that ibuprofen is not soluble in water and "as such would necessarily be suspended in [] syrup" (*Id.*)

The Examiner then concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a suspension base." (*Id.*)

As is fundamental, a *prima facie* case of obviousness must be based on facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (C.C.P.A. 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (B.P.A.I. 1993).

"Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. See Ruiz v. A.B. Chance Co., 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed. Cir. 2000); ATD Corp, 159 F.3d at 546, 48 USPQ2d at 1329; Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.").

For a *prima facie* case of obvioiusness to be established, the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art. *See In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976). The

mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness. *See In re Fritch*, 23 USPQ 1780, 1783 (Fed. Cir. 1992).

It is respectfully submitted that it is not seen where the record contains any facts to support the Examiner conclusory statement that having ibuprofen, which is water insoluble, in a syrup would necessarily lead to the ibuprofen being suspended in the syrup.

First, the Examiner's conclusion is premised on the fact that the syrup must have water. There are no facts in the record made by Examiner nor can it located where the syrup disclosed by Sunshine would have any water in it.

Second, even if it did disclose water, which is not agreed with for the above reasons, merely disclosing a water insoluble compound in water does not make a suspension. It is respectfully submitted that such a disclosure would disclose a syrup that would require the composition to be shaken to disperse the water insoluble compound in the syrup as the water insoluble compound would fall out of the syrup over time. Such a syrup would not be a suspension.

Finally, it is not seen where, among other things, any combination of a taste masking compound and at least one suspension agent in combination are disclosed as being useful in a suspension, much less in a syrup.

For these reasons, the rejection is improper and should be withdrawn.

Additionally, the Examiner cites Sunshine column 12-13, lines 50-9, for the proposition that Sunshine discloses a "preserved syrup formulation." With all due respect, Sunshine only has 8 columns and the Reexamination Certificate has 4 columns. It is not seen where columns 12-13 can be found. Nor can it be found where the words "preserved syrup formulation" are written in Sunshine.

For these additional reasons, the rejection is improper and should be withdrawn.

2) The Examiner acknowledged that Sunshine's disclosed ibuprofen range is differs from the range claimed in claims 25 and 33 of the captioned application.

To fill the acknowledged gap, the Examiner merely reasoned that "anyone of ordinary skill in the art will appreciated [that] preferred dosages are merely exemplary and serve as useful guideposts for the physician. (Office Action at 4.)

Claims 25 and 33 depend from claims 1 an d 29. Because the rejection of claims 1 and 29 are improper for the reasons set forth above, the instant rejection is also improper and should be withdrawn.

3) Regarding claims 26-28 and 34, the Examiner merely concluded that "it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable."

The record is unclear just what the precise basis is for the Examiner's rejection of claims 26-28 and 34-36 of the captioned application. Contrary to the Examiner's assertion concerning the scope of claims 26-28 and 34-36, the claims are directed to compositions and suspensions having various properties, including the claimed CMAX and AUC values. As admitted by the Examiner, Sunshine does not disclose a suspension. Because Sunshine does not disclose, among other things, a composition including, among other things a taste masking agent and at least one suspending agent or a suspension as claimed in the captioned application, it is not seen where the claimed subject matter is an "old product", particularly if it had not been described or suggested before the caption application was filed. For this reason the rejection is improper and should be withdrawn.

Additionally, claims 26-28 and 34-36 depend from claims 1 an d 29. Because the rejection of claims 1 and 29 are improper for the reasons set forth above, the instant rejection is also improper and should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

By: _____
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DATE: August 4, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gelotte et al.

Serial No.: 10/607,889 Art Unit: 1614

Filed : June 26, 2003 Examiner: D. A. Jagoe

For : RAPIDLY ABSORBED LIQUID COMPOSITIONS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

August 4, 2004
(Date of Deposit)

Timothy E. Tracy
(Name of applicant, assignee, or Registered Representative

(Signature)

August 4, 2004
(Date of Signature)

Commissioner For Patents
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PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicants petition the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 9, 2004 for two(2) months from June 9, 2004 to August 9, 2004. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-0750/MCP-275 CON 1/TET in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

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01 FC:1252 420.00 DA

Respectfully submitted,

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